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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/932,227	09/17/1997	ERIC T. FOSSEL		5092

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440 COMMERCIAL STREET
BOSTON, MA 02109

EXAMINER

MULLIS, JEFFREY C

ART UNIT	PAPER NUMBER
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1711

DATE MAILED: 09/08/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 08/932,227	Applicant(s) FOSSEL, ERIC T.	
	Examiner Jeffrey C. Mullis	Art Unit 1711	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 June 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 33-35, 38-44, 47-53, 56-59, 61-67 and 69-81 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 33-35, 38-44, 47-53, 56-59, 61-67 and 69-81 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date <u>6-16-05</u> . | 6) <input type="checkbox"/> Other: _____ |

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Claims 64-67 and 69 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The treatment of bed confinement was not present in the specification as filed and is therefore new matter.

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claim 64 is rejected under 35 U.S.C. 102(b) as being anticipated by Saavedra et al. (U.S. 5,632,981).

Saavedra et al. disclose a process for treating impotence in which nitric oxide releasing material is incorporated into a condom (column 10 lines 20-35). The composition may be in the form of liposomes in a gel or patch at column 9 lines 51-65 and applied topically (column 11 lines 16-26) and may be non-aqueous (note the paragraph bridging columns 11 and 12) since the phosphate buffer (a salt containing material) may be added at column 12 lines 48-56, or "saline" may be added at column 11 lines 40-52.

Claims 65 and 66 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Saavedra, cited above.

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Saavedra does not explicitly recite "selecting a means of producing a hostile biophysical environment which increases the migration of the nitric oxide precursor means into the skin". However since salt containing materials are used in the treatment process of Saavedra and since salt containing materials are disclosed by applicant to produce such a function, it would reasonably appear that Saavedra's process inherently meets applicant's limitation.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP ' 2112-2112.02.

Claims 33, 34, 64 and 70-73 are rejected under 35 U.S.C. 102(a) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Biurope Societe (FR 2,740,453).

Patentees in the examples on page 24 disclose an L-arginine composition containing sodium chloride in applicants concentrations (and therefore presumed to inherently capable of producing a hostile biophysical environment). Note that the last paragraph on page 2 and first paragraph on page 3 as well as the abstract discloses that the compositions are useful topically as creams and emulsions for combating aging.

When the reference discloses all the limitations of a claim except a property or function, and the Examiner cannot determine whether or not the reference inherently possesses properties which anticipate or render obvious the claimed invention, basis exists for shifting the burden of proof to applicant. Note

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In re Fitzgerald et al. 619 F. 2d 67, 70, 205 USPQ 594, 596, (CCPA 1980). See MPEP § 2112-2112.02.

The non-statutory double patenting rejection, whether of the obviousness-type or non-obviousness-type, is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent. *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); and *In re Goodman*, 29 USPQ 2d 2010 (Fed. Cir. 1993).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(b) and (c) may be used to overcome an actual or provisional rejection based on a non-statutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.78(d).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 33-35, 38-41, 61 and 64-78 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-11 of U.S. Patent No. 6,207,713. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of increasing blood flow is encompassed by the method of increasing blood flow of the patent claims.

Claims 33-35 38-44 47-53 56-59 61-67 and 69-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-9 of U.S. Patent No. 5,895,658. Although the

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conflicting claims are not identical, they are not patentably distinct from each other because the scope of the claims overlap and applicants specific diseases or conditions are disclosed to be treatable by the method claimed in the patent claims by the patent specification as are applicants specific vehicles and thus this information supports the patent claims and is properly viewed as part of the patent claims .

Claims 33-41 51-53 56 57-59 61 67 69-73 78-81 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 6,458,841. Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of promoting hair growth involves topical application of applicants materials and therefore presumably effects blood flow as in the claims, the use of dermal patches is disclosed by the patent specification as a means to practice the claimed method and therefore can be said to support the patent claims.

Claims 33-41 61-63 70-73 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-10 of U.S. Patent No. 5,922,332. Although the conflicting claims are not identical, they are not patentably distinct from each other because Although the conflicting claims are not identical, they are not patentably distinct from each other because the method of promoting hair growth involves topical application of applicants materials and therefore presumably effects blood flow as in the claims, the use of dermal patches is disclosed by the patent specification as a means to

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practice the claimed method and therefore can be said to support the patent claims.

Claims 33-35, 38-44, 47-53, 56-59, 61-67 and 69-81 are provisionally rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-15 of copending Application No. 10/201635. Although the conflicting claims are not identical, they are not patentably distinct from each other because the salts recited by the copending application are disclosed by the instant application to inherently act to produce a hostile biophysical environment and such would therefore be inherent in the copending claims.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Applicant's arguments filed 6-16-05 have been fully considered but they are not persuasive. With re to "bed confinement" applicants have not pointed out support in the specification as filed. The examiner did not nor was required to review the substitute specification for new matter.

Saavedra discloses a liquid for topical application and any liquid for topical application can be reasonably be said to be a lotion or ointment.

The examiner regrets that Office personnel have not processed applicant's terminal disclaimer so that it can be considered. However personnel responsible for dealing with the matter have been notified.

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The above new grounds of rejection under 35 USC 102/103 as well as obviousness type double patenting was made relying on art submitted by applicants after the payment of a 1.17(p) fee and is therefor made FINAL, MPEP 609.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey Mullis whose telephone number is (571) 272-1075. The examiner can normally be reached on Monday-Friday from 9:30 to 6:30.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Seidleck, can be reached on (571) 272-1078. The fax phone number for this Group is (703) 872-9306.

JCM

9-1-05

Jeffrey Mullis
Primary Examiner
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A handwritten signature in black ink, appearing to be 'JM', located below the printed name of the examiner.